Фармацевтичний форум «Клінічні випробування в Україні. Європейська інтеграція»

Клінічні дослідження в екстремальних умовах. Інновації перевірені війною.

Clinical Trials in Extreme Conditions. Innovations Tested by the War.

Prof. Igor Bondarenko Head of Oncology and Medical Radiology Department Dnipro State Medical University, Ukraine

Mercure Kyiv Congress, June 29, 2023



# Before 24 February 2022

Ukraine was perfect place for clinical trials performance

# After 24 February 2022

Main aim is to help patients and save the data for Sponsors

 Majority of sites continues • About 2500 patients' treatment in clinical research sites Chernihiv & Sumy Rivne Lutsk trials Zhytomyr KŸĪV Poltava Lviv 🔍 Khmelnytsky~ Kharkiv Luhansk Around 500 Ternopil @ Cherkasy New patients' randomization is Vinnytsya Ivanoclinical trials Dnipropetrovsk Donetsk Frankivs Kirovohrad Chernivtsi not allowed Zaporizhzhy Mykolayiv desa Kherson Approximately No new clinical trials started 40-50% were Simferopol within the war period oncology trials

Ukraine has been receiving unprecedented support from civilized World. Thank you to all of you!



Most of the clinical trials will be completed within 2-3 months.

This is a great challenge for hundreds of experienced specialists and thousands of patients.

Ukraine has safe locations to conduct new clinical trials.

Sponsors Companies of clinical trials – please come back to Ukraine.

This will be the best solidarity reflection with Ukraine!



## **Clinical Trials Statistics**



#### CLINICAL TRIALS BECOME HARDER TO CONDUCT

## CLINICAL TRIALS

NEWS PUBLICATIONS - MEDIA - CONFERENCES - COLUMNS - RESOURCES - WEBCASTS SUBSCRIBE -

## Phesi Report: Assessing Single Patient Investigator Sites in Cancer Clinical Trials

Published on: January 25, 2023 Gen Li, PhD, MBA



Already existing enrollment challenges emphasized by single patient sites.

Patient enrollment performance is a chronic challenge in clinical development. Three years of the COVID-19 pandemic has caused a number of investigators to back out from participating in clinical trials, and the war in Ukraine has reduced geographic coverage for trials in various indications. Moreover, a global economic downturn and intensifying global inflation have made already costly clinical trials more expensive.

In this report, we leverage site level patient enrollment data in Phesi's Trial Accelerator platform to assess the number of investigator sites that have recruited only one patient, the impact from those sites, and possible methods to improve enrollment.

#### The dataset



Gen Li

A total of 173 cancer clinical trials with site level enrollment data, the majority conducted in the past three years, are included in this analysis. Most of the trials

severely impacted by COVID-19 are not included. Overall, cancer trials take at least three years to complete and publish results; the cancer trials started before or during the pandemic and affected by the shutdown do not yet have available enrollment data. In the dataset, there are 11,826 investigator sites that enrolled one or more patients, totaling 83,916 patients.

## Phesi and Tufts CSDD analysis of 173 cancer trials



# CUNICAL TRIALS NEWS PUBLICATIONS - MEDIA - CONFERENCES - COLUMNS - RESOURCES - WEBCASTS SUBSCRIBE -

### Case study: Examples of successful enrollment

Igor Bondarenko, MD, PhD, from Ukraine is one of the most prolific investigators among the 173 trials. He enrolled 113 patients for the 11 trials in which he participated. The median number of patients he enrolled is nine. There is no trial where he enrolled only a single patient.



# Is it possible to conduct clinical trials during war?

## Workload of Professor Igor Bondarenko site (Dnipro, Ukraine) since 24.02.2022 (martial law period)

- Total number of conducted clinical trials 44
- Total number of patient's visits 3987
- Laboratory tests 3291
- Intravenous infusions 1800
- IP (tablets ) dispensing 1048
- Injections 179
- ECG 831
- CT examinations (tumor assessment) 1117
- Telephone Follow Up 861



## I AM PROUD OF MY TEAM!

# **Highly Cited Researchers (329) in Oncology**

Country	Number of HCRs	Country	Number of HCRs
United States	140	Canada	3
France	15	Japan	3
Germany	15	Netherlands	3
United Kingdom	12	Switzerland	3
Italy	10	Ukraine	1
Republic of Korea	10	Greece	1
Australia	8	Poland	1
Spain	6	Singapore	1
China	5	Taiwan	1
Belgium	3		

# Institutions with Highly Cited Researchers in Oncology

Institution	Number of HCRs	Institution	Number of HCRs
Memorial Sloan Kettering Cancer Center, United States	45	Institute of Cancer Research - UK, United Kingdom	2
UTMD Anderson Cancer Center, United States	22	Seoul National University (SNU), Republic of Korea	2
Dana-Farber Cancer Institute, United States	10	Yonsei University, Republic of Korea	2
Harvard University, United States	9	Kindai University (Kinki University), Japan	2
Universite Paris Saclay, France	7	Asan Medical Center, Republic of Korea	1
American Cancer Society, United States	4	Chungbuk National University, Republic of Korea	1
Yale University, United States	3	University of Montreal, Canada	1
University of Sydney, Australia	3	Netherlands Cancer Institute, Netherlands	1
University of Milan, Italy	3	University of Zurich, Switzerland	1
Sungkyunkwan University (SKKU), Republic of Korea	3	National & Kapodistrian University of Athens, Greece	1
 University of Barcelona, Spain	2	Ulsan National Institute of Science & Technology (UNIST), Republic of Korea	1
Dnipro State Medical University, Ukraine	1	Nanyang Technological University, Singapore	1
		National Taiwan University, Taiwan	1

Clarivate <sup>®</sup>	Wh	o we serve 👻 Pro	oducts & Services 🔻	Resources	<ul> <li>Contact</li> </ul>
Highly Cited Researchers	2022 Recipients	Researcher stories	Analysis M	lethodology	Past lists FA
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FULL NAME CATEGORY	PRIMARY AFFILIATION		SECONDARY AFFIL	IATIONS	
B Bondarenko, Igor M. Clinical Medicine	Dnipropetrovsk State Medical Academy,	Ukraine			View Profile

## **Clinical Trials Challenges During War in Ukraine**

## **Human Resources**

**Patients relocation** makes further participation in trial less possible

Site's staff relocation causes the lack of experienced investigators and coordinators

Inability to perform clinical trial activity in sites close to battle fields

### **Data Resources**

Logistic issues causes **delayed in sample handling** and sites supply

CRO and sites have to adapt quick solutions to **enable** remote monitoring

High **risk of data loss** due to air attacks



2

# **New Paradigm** for future clinical trial process

Fast

Less Expensive

More Accurate

Motivate Site

**Remote Technologies** 

#### Assist

Sponsor creates protocol and Site Assistant System for all sites around the world

Create

One **super template** for specific clinical trial for all involved sites

Interact

### Multi-lingual system provides easy communication



## 2.2 Research project description template EURIZON FELLOWSHIP PROGRAMME "Remote Research Grants"

Valid applications need to be submitted through the website: <u>https://indico.desy.de/event/38700/</u> by the Principal Investigator of the Ukrainian team before May 8<sup>th</sup> 2023 at 12:00 Pm (noon) CEST time. Before applying please read carefully the Terms of Reference (ToR).

Title<sup>1</sup> of the research project: (max 30 words)

Developing a new paradigm for conducting oncology clinical trials during emergencies

submitted by

#### PRINCIPAL INVESTIGATOR (PI)<sup>2</sup>:

First name and Family name	Igor <u>Bondarenko</u>
(English)	

		What should be done?
æ	Step 01	What should be done?
		Investigate research site problems
Ø	Step 02	
		Learn the experience of successful site
(2) (2)	Step 03	
		Implement appropriate software solutions
	Step 04	
		Share applied principles with others

### SITE ACTIVITIES' PROBLEMS

Quality of data and timing in complex
trials

- 2 Safe drug storage and accountability
- 3 No on-site monitoring
- 4 Accuracy and timing of payments
- 5 Fast and quality communication

## SITE SOLUTIONS - NEW SOFTWARE Clinical Trials Site Management System (CTSMS) - MCR



# CTSMS

# **Clinical Trials Site Management System**

one step ahead to open the future of clinical trials



 $\uparrow$ 

лh

#



ADVARRA



**REA** 





Focused on Site Activities + Sponsor Activities and CRO Activities

Focused on Sponsor Activities and CRO Activities





CLINICAL TRIAL MANAGEMENT SYSTEMS



#### COMPETITION

MCR

#### Site Activities

- ✓ Site departments workflow
- ✓ Each department has it own dashboard
- ✓ In-depth planning
- ✓ Procedures' execution control
- ✓ Medical documents creation
- ✓ Drug storage and accountability
- Complete principal investigator awareness
- Possibility to auto complete EDC from CTSMS
- ✓ Remote monitoring
- Trials procedures tracking and invoicing
- ✓ LEC/IRB communication tool
- ✓ All solutions in one system



# CLOUDBYZ

#### Sponsor/ CRO Activities

- General planning
- Data capture solutions
- Overall statistics
- Budgeting







TRIAL MANAGEMENT





# MCR - Smart clinical trials site management Platform

aimed to coordinate and arrange all activities from site selection through trial conduction to authorities' inspection

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Po	liglo	t			
		Abbr	Language		Text
1		en	English	▶ ●	Thank you all for your attention! We wish peace and prosperity!
2		uk	Ukrainian	►	Дякуємо всім за увагу! Бажаємо миру та процвітання!
3		ru	Russian	▶●	Благодарим всех за внимание ! Желаем мира и процветания !
4		de	Deutsch	▶◀》	Vielen Dank für Ihre Aufmerksamkeit! Wir wünschen Frieden und Wohlstand!
5		pl	Polish	▶◀》	Dziękuję wszystkim za uwagę! Życzymy pokoju i pomyślności!
6		it	Italian	▶◀》	Grazie a tutti per l'attenzione! Auguriamo pace e prosperità!
7		es	Spanish	▶◀》	¡Gracias a todos por su atención! ¡Deseamos paz y prosperidad!
8		fr	French	▶◀》	Merci à tous pour votre attention ! Nous souhaitons la paix et la prospérité!
9		nl	Nederlands	▶◀》	Dank u allemaal voor uw aandacht! Wij wensen vrede en voorspoed!
10		pt	Portuguese	▶◀》	Obrigado a todos pela atenção! Desejamos paz e prosperidade!
11		CS	Czech	►	Děkuji všem za pozornost! Přejeme mír a prosperitu!
12		tr	Turkish	►	İlginiz için hepinize teşekkür ederim! Barış ve refah diliyoruz!
13		he	Hebrew	►	תודה לכולכם על תשומת הלב! אנו מאחלים שלום ושגשוג!
14		zh	Chinese	▶◀》	谢谢大家的关注!我们祝和平与繁荣!
15		ar	Arabic	►	إشكرا لكم جميعا على اهتمامكم! نتمنى السلام والازدهار
16		ja	Japanese	▶●	ご <b>清</b> 聴ありがとうございました!私たちは平和と繁栄を願っています!
17		ko	Korean	▶◀》	관심을 가져 주셔서 감사합니다! 우리는 평화와 번영을 기원합니다!

## Available Site Solutions

eConsent ePRO/eCOA eSource eSiteFile Telehealth Recruitment portals Remote monitoring

cover SOME processes aroundresearchsiteandNOprocesses wihtin the site

## **Site Crucial Processes**



Site Departments' Activities Planning



Tracking and Controlling of all ongoing Processes



Coordinating Site's Team and Units



Source Recording of Protocol Specific Data



**Financial Tracking and Motivation** 

# **Essential MCR Services**

## 01

**Deep planning** Full protocol and site activities scheduling

#### MCR - Smart clinical trials site management Platform

aimed to coordinate and arrange all activities from site selection through trial conduction to authorities' inspection

# 02

All activities control Supervise each step in trial conduction

## 03

Create medical documentation Quality and accuracy of data



## 04

Remote mode of work Remote Data-management and monitoring

## 05

Automated invoicing

100% automated payments managements

## 06

7

Multilanguage usage

User interface and documents creation in at least 17 languages

### MCR COVERS THE WORK OF ALL DEPARTMENTS



# **MIS – Medical Information Systems**



### DEEP PLANNING

### Use study schedule

Adjust site routine activities

Inform internal departments

Form the base for all time points

15 Key Questions
 0 for Site Initiation Visit

Analysis deep planning example

21 parameters are required to plan one analysis

Analy	sis parameters	EOT > Q2 Solution	(QL) > Blood for Plasma Biomarker Analys	ies)
-------	----------------	-------------------	--	------

Parameter	Value
Analysis name	Blood for Plasma Biomarker Analyses
Ambient/frozen	Ambient
Component	Plasma
Uphold	No
Uphold, min	0
Centrifuge process	No
Centrifuge process, min.	0
Cold centrifuge	No
Centrifuge speed. rot/min	0
Centrifuge turn	0
Storage temperature	0

Test tubes												
Name					Caral					Tir	ne	
Lab kit	Tube/	Amount	t,⁰C	C Courier	send in	Pre-/ post dose	Drug	Starting point	Fr	om	t	0
Lad Kit	slide				, days				t	m	t	m

### ACTIVITIES CONTROL

All planned activities appear on the day schedule. Once the procedure is marked as done, the time of completions will be saved

Regi	Que	Lab	ECG	Exa	СТ	Chemothe	Injec	TAB	Sympt	B	Call
	0/1	0/6	0/1	8 / 0	0/0	0/5	0/0	0/3	0/2		0/3
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### MEDICAL RECORDS CREATION





Patient record is divided according to standard procedures and each section is placed chronologically based on sequence order

elect data from drop-down menu or	Data Group Scheduled Visit?:	Yes v 🗶	
Enter data manually	Sentence:	hospitalized	- X
	Sentence 2:	for the first course of treatment $$ ×	- X
	1		

and site assistant will create the sentence

Patient was hospitalized for the first cycles of treatment within the scheduled time frame

#### TEMPLATING

#### **Study Protocol**

Lorem ipsum dotor sit amet, Sed sequi nostrum hic capiditate voluptatem qui amet magnam qui minus internos quo doloremque provident. Ex quibusdam libero est quos omnis qui voluptate digrissimos ea voluptatem capiditate ea quidem minus et deleniti distinctio et alias assumenda.

PK postdose must be collected at the end of IP infusion, 2 and 4 hours after the end of IP infusion.

qui maiores iure est magni aperiam. Cum perferendis nihi vei consequatur dolorum ea digrissimos consequatur. Et excepturi perferendis aut soluta debitis sed deleniti eveniet eum blanditiis aspernatur eum dolores eius et obcaecat enm. Ut quibusdam iste eos officia doloremque et aliquid molestias.

Any protocol-specific data can be added to medical record template for a particular study and doctor will never forget to evaluate such data

	Actio	on order (Ten	nplate: M )		
		Drug	Form	Prompt	Text
	7	Μ	Text	Введення препарату виконувалося в праву/ліву ліктьову вену.	Введення препарату виконувалося в <b>праву/</b> <b>ліву</b> ліктьову вену.
	8	M	Summary of input		
	9	M	Patient data	в кінці інфузії (EOI) (± 10 хвилин)	
	10	М	/Postdose	End of M <sup>,</sup> infusion (+ 10 min)	
$\backslash$	11	M	Patient data	через 1 годину (± 10 хвилин) після завершення інфузії.	
	12	м	/Postdose	2 hours after end of M infusion (± 10 min)	
	13	М	Patient data	через 3 години (± 10 хвилин) після завершення інфузії.	
	14	М	/Postdose	4 hours after end of M infusion ± 10 min	

### EDC/eCRF DATA

			Пацієнт планово прибув до клініки для візиту спостереження. Загальний стан пацієнта задовільний, без негативної динаміки з попереднього візиту.
Date PK/Pp (Vital Signs) Medication Recust	Vital Signs – Day 1 Cycle 12 Date of vital signs Weight Systolic blood pressure Diastolic blood pressure Heart rate Temperature	mmig mmig bass/	У 08:20 пацієнт здав аналіз крові у центральну лабораторія (Q2Solution) Скарги. Нових скарг не пред'являє. Попередні скарги зберігаються без динаміки. Об'єкличено о 08:40 AT: 126/73 мм рт. ст., Пульс: 65 /хв., Чдс: 65 /хв.; ЧД: 16 /хв.; Температура тіла (аксилярно): 36.3 °C Винірювання вітальних функцій проведені в положенні хворого сидячи, після 5 хв. відпочинку. Вага : 78.5 кг.; Площа тіла (за формулою Мостеплер) = 1.97 м². ECOG - 1 бал. Нових змін при огляді в порівнянні з попереднім візитом - не виявлено. При огляді вбрігаться: з зиковняя маси тіла на 10%, в порівнянні з скринінгом (CS). St. Ioc. без змін: без динамиях.
		Save Cancel	Негативні явища - сниження ваги 2 ст. СТС з 26.10.2021, не вирішилось. Серйозних негативних явищ немає. Супутня терапія- не приймає
			КТ Пацієнту виконано планову СКТ <u>: ОГК без контраєтування.</u> Висновок від радіолога на даний момент не отриманий. За техничних причин, виконати МРТ ОЧП та ОМТ не можливо. Пацієнт записан на дослідження 06.10.2022.
	_		Висновок: 3 пацієнтом проведена бесіда, що при появі нових скарг, погіршенні самопочуття - своєчасно інформувати лікаря-дослідника. Рекомендовано споствреження онколога, сімейного пікаря за м/проживання. Продовжувати прийом раніше призначеногі супутньої тералії, гідно з рекомендаціями. Дата наступного візиту: 06.10.2022 / МРТ ОЧП та ОМТ Пацієнт в заповільному стані відполизенняй полому самостійно

## Identify data you need in EDC/eCRF and MCR will highlight it in source and/or transfer it

### **REMOTE WORKFLOW**



Any data collected on site, including paper source documents, is transformed into certified copy, which allows 100% remote activities with such data

### AUTOMATED INVOICING



#### ACTIVE PATIENTS PER MONTH/YEAR CHART

**2011** – «Deep Planning» tool was implemented

**Real Data From Site** 

2014 – «Medical Records Creation» tool was implemented

**2019** – Starting to analyze statistical data from MCR

Every implemented module of MCR significantly improves productivity and integrity of a research site



#### PROCEDURE AVERAGE START TIME PER DAY



Only well-measured, thought-through planning and coordination with MCR tools helps us to perform more procedures per day within the same number of resources



#### NUMBER OR PROCEDURES DONE PER YEAR



MCR helps to sophisticate advancements and increase departments' workflow.

Since 2012 MCR is actively used at our testing research site and shows amazing progress.

# **KNOWLEDGE CENTER**

Videos & Presentations

Manuals & Handouts



Live Meeting & Conferences







## Who needs knowledge center?

# Sites

Regardless of experience

# Sponsors

Intending to increase site productivity

# Beginners

Who knows little or nothing about trials

# Everyone

Who wants to join the community

# **MENTOR SERVICE**



## **Evaluation team**

## b Coordination team

## Support team

# Mentor Service Workflow



## How can we cooperate?

Learn your mode of work

Present our mode of work

Mutual development implementation

Promote new paradigm of clinical trial conduction

Grant support of CTSMS MCR

## Gratitude to our partners all around the world !

Д КЗ «Дніпро	3 «Дніпропетро Кафедра опетровська міс	овська медична ак онкології та медич ська багатопрофіл Центр хіміотера ТОВ «Ар Ді Пі-Юкре	адемія МОЗ іної радіоло ьна клінічна пії ейн»	України» огії а лікарня №4» ДОГ	
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## OUR ACHIEVEMENTS SINCE 2002







Dnipro State Medical University,

City Clinical Hospital #4,

Dnipro, Ukraine

# **8** 4980 **5**20 **CLINICAL TRIALS** $\mathbf{\nabla}$ 31 TOP ENROLLMENT 150 3 FDA INSPECTIONS 430



Ukraine is thankful to the whole world for the help and support

We want to contribute clinical trials

Now it is our time to share our knowledge and provide our solutions for current clinical trial related issues

## Let innovate together Please join us!

Professor Igor Bondarenko Dnipro, Ukraine <u>oncology@dmu.edu.ua</u> +38 (067) 562 50 54